DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 13 1986

Re: Buspar
Docket No. 86E-0456

#14

Charles E. Van Horn, Esq.
Director, Patent Examining Group 120
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the application for patent extension for U.S. Patent No. 4,182,763, filed by Mead Johnson & Company, under the patent extension provisions of 35 U.S.C. §156 et seq. The human drug product claimed by the patent is Buspar (Buspirone hydrochloride), New Drug Application (NDA) 18-731.

A review of the Food and Drug Administration's official records indicates that Buspar, the product identified in the patent extension application, was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. §156(a)(4). Our records also indicate that NDA 18-731 represents the first permitted commercial marketing or use of the active ingredient, Buspirone hydrochloride. The NDA was approved on September 29, 1986 which makes the submission of the patent extension application on October 27, 1986 timely within 35 U.S.C. §156(d)(1).

Should you conclude that the subject patent is eligible for patent extension, please advise us accordingly. As required by 35 U.S.C. §156(d)(2)(A), we will then determine the applicable regulatory review period, publish that determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Isaac Jarkovsky, Esq.
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